

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/530,464	NYLESE, TARA	
	<b>Examiner</b>	<b>Art Unit</b>	
	JACQUELINE DIRAMIO	1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's amendments and arguments filed 11/5/2009.
2. ☒ The allowed claim(s) is/are 1,10,11,15,16,18-21 and 25-29 (renumbered as claims 1-14, respectively).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).  
\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.  
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached  
1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.  
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.  
**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application  |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>20091112</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input type="checkbox"/> Examiner's Amendment/Comment   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                         |
|  | 9. <input type="checkbox"/> Other _____.   |

/Mark L. Shibuya/  
Supervisory Patent Examiner, Art Unit 1641

## **DETAILED ACTION**

### ***Status of the Claims***

1. Applicant's amendments to claims 1, 10, 20, and 25 are acknowledged and entered.
2. Currently, claims 1, 10, 11, 15, 16, 18 – 21, and 25 – 29 are pending and considered allowable.

### ***Withdrawn Rejections***

3. All previous rejections of the claims under 35 U.S.C. 112, second paragraph, are withdrawn in view of Applicant's amendments filed November 5, 2009.
4. All previous rejections of the claims under 35 U.S.C. 103(a) are withdrawn in view of Applicant's arguments filed November 5, 2009. In particular, Applicant's arguments (see pages 8-12) that it would not have been obvious to one of ordinary skill in the art to utilize the ELISA-type test of Rutanen (US 2005/0136490), which detects one particular concentration of an analyte at a particular time period, in a lateral-flow type of test that includes a plurality of regions in order to detect various levels of analyte concentration, and read on Applicant's claimed invention is found persuasive. Therefore, all previous rejections have been withdrawn.

## **REASONS FOR ALLOWANCE**

5. The following is an examiner's statement of reasons for allowance:

The prior art fails to teach or suggest a method for monitoring whether an **abnormal** change occurs in a health condition based on whether a change in a level of analyte concentration occurs in a source, comprising:

providing multiple unitary test devices, each unitary test device including a plurality of regions, each region responsive at a different sensitivity level to indicate the presence of the analyte in the source;

bringing a first sample from the source into contact with a first of the unitary test devices at a first time, there being a visually observable response in one or more regions of the first test device if the source contains at least a minimum level of analyte concentration; and

subsequently bringing a second and different sample from the same source into contact with a second of the unitary test devices at a second time to determine whether a change in the health condition occurs based on whether an abnormal change in analyte level occurs by the second time, there again being a visually observable response in one or more regions of the second test device if the source contains at least a minimum level of analyte concentration, wherein determination of whether the health condition changes adversely is based on capillary flow of each sample from a sample receiving region on one of the first or second test devices to one or more of the plurality of regions on the same test device and the response on each device is based on an amount of binding of an antigen and an antibody to form complexes.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE DIRAMIO whose telephone number is (571)272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline DiRamio/  
Examiner, Art Unit 1641

/Mark L. Shibuya/  
Supervisory Patent Examiner, Art Unit 1641